



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1143]

Draft Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus From Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled “Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus From Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps),” dated October 2013. The draft guidance document provides establishments that make donor eligibility determinations for donors of HCT/Ps, with recommendations for donor testing for West Nile Virus (WNV) using an FDA-licensed donor screening test. The guidance recommends the use of an FDA-licensed nucleic acid test (NAT) for testing donors of HCT/Ps for infection with WNV. The draft guidance replaces the draft guidance entitled “Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus From Donors of Whole Blood and Blood Components Intended for Transfusion and Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” dated April 2008, with respect to HCT/Ps. The testing recommendations in the guidance, when finalized, will supplement the donor screening recommendations for WNV (which will remain in place) that were made in the guidance entitled “Guidance for Industry:

Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” dated August 2007 (2007 Donor Eligibility Guidance).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Chacko, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled “Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus From Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps),” dated October 2013. FDA is providing establishments that make donor eligibility determinations for donors of HCT/Ps with recommendations for donor testing for WNV using an FDA-licensed donor screening test. FDA believes that the use of an FDA-licensed NAT will reduce the risk of transmission of WNV from donors of HCT/Ps and therefore recommends that you use an FDA-licensed NAT for testing donors of HCT/Ps for infection with WNV. The 2007 Donor Eligibility Guidance indicated that FDA may recommend routine use of an appropriate, licensed donor screening test(s) to detect acute infections with WNV using NAT technology, once such tests were available.

The draft guidance announced in this notice replaces the draft guidance entitled “Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus From Donors of Whole Blood and Blood Components Intended for Transfusion and Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” dated April 2008 (April 28, 2008; 73 FR 22958), with respect to HCT/Ps. The testing recommendations in the guidance, when finalized, will supplement the donor screening recommendations for WNV (which remain in place) that were made in the 2007 Donor Eligibility Guidance.

The draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents FDA’s current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the

public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit either electronic comments regarding this document <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: October 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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